

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION**

THIS DOCUMENT RELATES TO:

All Cases

**MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)**

**[Leave to File Granted
December 22, 2015]**

**STOPNC DEFENDANTS' SUPPLEMENTAL BRIEF ADDRESSING
TWO QUESTIONS FROM THE BENCH AT ORAL ARGUMENT
ON PRIVILEGE ISSUES REGARDING MICHAEL O'NEAL**

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (collectively "STOPNC Defendants"), file this short supplemental brief to address two questions raised by the Court at the December 17, 2015, oral argument on Doc. 2437¹ and Doc. 2469². The questions were not addressed directly in the briefing. Citations to authority mentioned at the oral hearing are provided below.

1. Who holds the privilege?

The Court asked counsel who holds the privilege found in the Tennessee Patient Safety and Quality Improvement Act. The STOPNC Defendants' position is that STOPNC, at least in part, holds the privilege. The Court asked whether there was case law under the old version of the statute that addressed this. Counsel mentioned "*Powell*."

¹ PSC's Motion to Compel Documents and Information from STOPNC's Pharmacy Consultant, Michael O'Neal.

² O'Neal's Motion for Protective Order.

In Tennessee, the person entitled to the benefit of a privilege may waive the privilege. *Powell v. Cmty. Health Sys., Inc.*, 312 S.W.3d 496, 512-13 (Tenn. 2010) (citing *Smith County Educ. Ass'n v. Anderson*, 676 S.W.2d 328, 333 (Tenn.1984)). The Supreme Court in *Powell* addressed “for whose benefit the peer review privilege exists,” and observed that “[t]he proper functioning of the peer review process hinges on the assurance to all persons participating in it — the members of the peer review committees, the persons under review, and the persons who provide information and opinions during the peer review process — that the information and opinions provided and discussed during the proceeding will remain confidential.” *Powell*, 312 S.W.3d at 512-13. The Supreme Court held that participants in the peer review process cannot waive the privilege. *Id.* at 513.

Previous case law also treated the privilege as being provided for the benefit of the health care provider. See *Eyring v. Fort Sanders Parkwest Med. Ctr.*, 991 S.W.2d 230, 240 (Tenn. 1999) (“[w]e have determined that the Peer Review Law *grants hospitals* both a qualified immunity from liability for damages and a privilege from discovery of the peer review process”) (emphasis added).

2. Does the TPSQIA’s legislative history address whether the TPSQIA was passed in response to *Lee Medical v. Beecher*?

The STOPNC Defendants noted in their briefing that the TPSQIA was passed in response to the Tennessee Supreme Court’s holding in *Lee Medical v. Beecher*, 312 S.W.3d 515 (Tenn. 2010). The Court asked whether the legislative history was consistent. Specific citations to legislative history on this point:

Statements of Senator Doug Overbey (sponsor):³

- “[The bill] seeks to put back into law the peer review process that we have known for years and years that the Supreme Court in a decision earlier this year called the confidentiality provisions into question. The law has been on the books since 1967 but has been rewritten about 11 times and I do agree with the Supreme Court saying we needed to take a comprehensive look at it.”⁴
- “[B]eing brought forward because of a decision of the Tennessee Supreme Court in June [*sic*] of last year that cast doubts about whether peer review material conducted in our health care facilities would remain confidential.”⁵
- “[The bill] rewrites the statute to put back in place the same protections that health care providers have always considered available to them in their patient safety efforts.”⁶

Statements of Representative Vance Dennis (sponsor):

- “Puts us back in the position we were before that court decision”⁷

* * * * *

Senator Overbey’s written statement on his website contemporaneous with the approval of the legislation in March 2011 confirms this:

Patient Safety / Peer Review — The full Senate approved legislation on Thursday to enact the Patient Safety and Quality Improvement Act of 2011. Senate Bill 484, as introduced and passed by the Senate, reverses a Tennessee Supreme Court decision in *Lee Medical, Inc. v. Beecher*, 312 S.W.3d 515 (Tenn. 2010), that overturned a major portion of the long-standing Tennessee peer review statute vital to health care providers in their efforts to improve patient safety and quality within their organizations. This legislation rewrites the peer statute to put back into place the same protections that health providers have always considered available to them in their patient safety efforts. The legislation maintains the same immunity provisions for participants in the quality improvement process as contained in the original peer review statute and

³ Links to the legislative history videos are at:
<http://wapp.capitol.tn.gov/apps/BillInfo/Default.aspx?BillNumber=HB1158&GA=107> (House)
<http://wapp.capitol.tn.gov/apps/BillInfo/default.aspx?BillNumber=SB0484&ga=107> (Senate).

⁴ 3/2/11 session, time 2:01:50-2:04:45.

⁵ 3/24/11 session, time 39:24-44:08.

⁶ 3/24/11 session, time 39:24-44:08.

⁷ 3/28/11 session, time 24:02-24:08.

explicitly defines which entities may create Quality Improvement Committees and claim the privilege that "peer review" documents are not subject to discovery.⁸

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The above citations to authority discussed at the hearing are offered to assist the Court on just these two questions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 23rd day of December, 2015.

/s/ Chris J. Tardio

Chris J. Tardio

⁸ "Capitol Update," March 24, 2011, available at: <http://www.senatordougoverbey.com/2011/03/28/capitol-update-march-24-2011/#sthash.WXXFgc8N.dpuf>.